

47.6-04

JFw

Practitioner's Docket No. U 014850-7

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application  
of

Inventor(s)

for

Title of invention

**OR**

In re application of: Vidya Bhushan LOHRAY, et al.

Serial No.: 10/697,926

Group No.: 1616

Filed: October 30, 2003

Examiner:

For: **HETEROCYCLIC COMPOUNDS, PROCESS FOR THEIR PREPARATION AND  
PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND THEIR USE IN  
THE TREATMENT OF DIABETES AND RELATED DISEASES**

**Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))**

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
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**37 C.F.R. 1.8(a)**

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**TRANSMISSION**

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Signature

JANET I. CORD

(type or print name of person certifying)

Date: JULY 23, 2004

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation; although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. 1.98(b):

- (1) *Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.*
- (2) *Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.*
- (3) *Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.*
- (4) *Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.*
- (5) *Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

**WARNING:** *No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).*

**NOTE:** *The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).*

### **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

**NOTE:** *"No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*


**NOTE:** *"An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** *"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

If a fee is required, please charge deposit account 12-0425.



SIGNATURE OF PRACTITIONER

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(type or print name of practitioner)

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New York, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Vidya Bhushan LOHRAY, et al.

Serial No.: 10/697,926

Group No.: 1616

Filed: October 30, 2003

Examiner.: -

For: HETEROCYCLIC COMPOUNDS, PROCESS FOR THEIR PREPARATION AND  
PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND THEIR USE IN  
THE TREATMENT OF DIABETES AND RELATED DISEASES

Attorney Docket No.: U 014850-7

**Commissioner for Patents**  
**P.O. BOX 1450**  
**ALEXANDRIA, VA. 22313**

Sir:

**INFORMATION DISCLOSURE STATEMENT**

We draw the attention of the Examiner to the attached references which were cited in  
U.S. Patent 6,310,069 upon which this case is a Reissue and which are also listed on the  
attached Form PTO-1449.

The PTO did not receive the following  
listed item(s) Ref. marked as: " \* "  
are missing

Respectfully submitted,

JANET I. CORD  
LADAS & PARRY  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NY 10023  
REG. NO.: 33778 (212) 708-1935

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***  
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**37 C.F.R. 1.10\***

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- ☐ transmitted by facsimile to the Patent and Trademark Office. to (703) 872-9306

Date: JULY 23, 2004

Signature

JANET I. CORD  
(type or print name of person certifying)

FORM PTO-1449

U. S DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 014850-7

10/697,926

APPLICANT

Vidya Bhushan LOHRAY et al.

FILING DATE

GROUP

10/30/2003

1616

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	4,342,771	08/1982	Schnur	
	AB	4,367,234	01/1983	Schnur	
	AC	4,725,610	02/1988	Meguro et al.	
	AD	4,873,255	10/1989	Yoshioka et al.	
	AE	5,002,953	03/1991	Hindley	
	AF	5,036,079	07/1991	Clark et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AG	570067	03/1985	AU		
	AH	008203	02/1980	EP		
*	AI	5355524	08/1984	EP		
	AJ	0139421	05/1985	EP		
	AK	0155845	09/1985	EP		
	AL	0207581	01/1987	EP		
*	AM	0236624	08/1993	EP		
	AN	0306228	03/1989	EP		
	AO	0332331	09/1989	EP		
	AP	0332332	09/1989	EP		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

*	AQ	Hisatome et al. CA 119:149791, abstract of <i>Chem. Lett.</i> (1993), 8: 1357-7022z
*	AR	Rise et al. CA 112: 98478, abstract of <i>Chem. Lett.</i> (1989), 43(5): 489-492
	AS	Khan, A. et al. CA 110:189420, abstract of <i>Pharmazie</i> (1988), 43(12): 864-865
	AT	Chemical Abstracts 93: 168217v (1980)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)	ATTY. DOCKET NO.	SERIAL NO.
	U 014850-7	10/697,926
	APPLICANT	
	Vidya Bhushan LOHRAY et al.	
	FILING DATE	GROUP
	10/30/2003	1616

REFERENCE DESIGNATION			U.S. PATENT DOCUMENTS		
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	5,037,842	08/1991	Goldstein	
	AB	5,130,379	07/1992	Clark et al.	
	AC	5,153,210	10/1992	Ainsworth et al.	
	AD	5,296,605	03/1994	de Nanteuil et al.	
	AE	5,330,999	07/1994	de Nanteuil et al.	
	AF	5,420,146	05/1995	Malamas et al.	

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AG	0337819	10/1989	EP		
	AH	0356214	02/1990	EP		
*	AI	0381371	08/1990	EP		
	AJ	0397453	11/1990	EP		
	AK	0415605	03/1991	EP		
	AL	0419035	03/1991	EP		
	AM	0428312	05/1991	EP		
	AN	0439321	07/1991	EP		
	AO	0441605	08/1991	EP		
	AP	0454501	09/2001	EP		

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)		
AQ	Shukla, J.S. and I. Ahman. "Synthesis of 2-Phenoxymethyl-3-(2'-pyridyl/thiazolyl)-4-quinazolones as Possible Antifertility Drugs." <i>Indian J. Chem.</i> (1979), 17B: 651-652	
AR	Husain, M.I. and E. Singh. "Some New 2-Aryloxymethyl-3- $\alpha$ -substituted Carboxymethyl-6,8-substituted-4-quinazolones as Possible Anticonvulsants." <i>Pharmazie</i> (1982), 37(H6): 408-410	
AS	Khan, A. and R.K. Saksena. "Synthesis and antibacterial activity of some new 2-aryloxymethyl-3-substituted-quinazolin-4-(3H)-ones." <i>Pharmazie</i> (1988), 43(H12): 864-865	
AT	de Nanteuil, G. "Euglycaemic and Biological Activities of Novel Thiazolidine-2,4-dione Derivatives." <i>Arzneim.-Forsch./Drug Res.</i> (1995), 45(II): 1176-1181	

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REFERENCE DESIGNATION			U.S. PATENT DOCUMENTS		
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	5,468,762	11/1995	Malamas et al.	
	AB	5,478,851	12/1995	Cantello et al.	
	AC	5,478,852	12/1995	Olefsky et al.	
	AD	5,478,853	12/1995	Regnier et al.	
	AE	5,480,896	01/1996	Malamas	
	AF	5,498,621	03/1996	Dow	

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AG	0528734	02/1993	EP		X
	AH	0543662	05/1993	EP		
	AI	0236624	10/1993	EP		
	AJ	0590793	04/1994	EP		
	AK	0604983	07/1994	EP		
	AL	0605228	07/1994	EP		
	AM	0612743	08/1994	EP		
	AN	0643050	03/1995	EP		
	AO	0645387	03/1995	EP		
	AP	0676398	10/1995	EP		

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)		
*	AQ	EP Patent 0528734 A1 dated February 24, 1993
*	AR	Whitcomb, R.W. "Thiazolidinediones." <i>Expert Opinion on Investigational Drugs</i> (1995), 4(12): 1299-1309
	AS	Messier, Claude and Michèle Gagnon. "Glucose regulation and cognitive functions: relation to Alzheimer's disease and diabetes", <i>Behavioral Brain Research</i> (1996), 75: 1-11
	AT	Clark, D.A. et al. "Substituted Dihydrobenzeopran..." <i>J. Med. Chem.</i> (1991), 34: 319-325

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	5,521,201	05/1996	Hindley et al.	
	AB	5,521,202	05/1996	Yano et al.	
	AC	5,710,152	01/1998	Nagao et al.	
	AD				
	AE				
	AF				

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AG	0678511	10/1995	EP		
	AH	0708098	04/1996	EP		
	AI	0733631	09/1996	EP		
	AJ	0745600	12/1996	EP		
	AK	0783888	07/1997	EP		
	AL	0787727	08/1997	EP		
*	AM	8528633	12/1986	GB		
	AN	62-175458	08/1987	JP		X
	AO	64-52765	02/1989	JP		
	AP	7138258	05/1995	JP		

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)		
	AQ	Dow, R. L. et al. "Benzyloxazolidine-2,4-diones as Potent Hypoglycemic Agents" <i>J. Med. Chem.</i> (1991), 34: 1538-1544
	AR	Japanese Patent 62-175458 dated August 1, 1987
	AS	Partial English translation of Japanese Patent 64-52765, dated February 28, 1989
	AT	Partial English translation of Japanese Patent 7138258 dated May 30, 1995

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	AC				
	AD				
	AE				
	AF				

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AG	2558473	11/1996	JP		X
	AH	0912575	01/1997	JP		X
	AI	9112003	08/1991	WO		
	AJ	9207838	05/1992	WO		
	AK	9207850	05/1992	WO		
	AL	9405659	03/1994	WO		
	AM	9425026	11/1994	WO		
	AN	9426720	11/1994	WO		
	AO	9507697	03/1995	WO		
	AP	9521608	08/1995	WO		

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)		
AQ	Japanese Patent 2558473 dated September 5, 1996	
AR	Japanese Patent 0912575 dated January 14, 1997	
AS	Hulin, Bernard et al. "Novel Thiazolidine-2,4-diones as Potent Euglycemic Agents", <i>J. Med. Chem.</i> (1992), 35(10): 1853-1864	
AT	Cantello, Barrie C.C. et al. <i>J. Med. Chem.</i> (1994), 37(23): 3977-3895	

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	<b>Vidya Bhushan LOHRAY et al.</b>	
	<b>FILING DATE</b>	<b>GROUP</b>
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					YES	NO
	AG	9526347	10/1995	WO		
	AH	9535108	12/1995	WO		
	AI	9605186	02/1996	WO		
	AJ	9611196	04/1996	WO		
	AK	9626207	08/1996	WO		
	AL	9741097	12/1996	WO		
	AM					
	AN					
	AO					
	AP					

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)		
	AQ	Sohda, T. et al. "Studies on Antidiabetic..." <i>J. Med. Chem.</i> (1992), 35(14): 2617-2626
	AR	Sohda, Takashi et al. "Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-Methylcyclohexyl-methoxy)-benzyl]thiazolidine-2,4-dione (ADD-3878) and Its Derivatives", <i>Chem. Pharm. Bull.</i> (1982), 30(10): 3580-3600
	AS	
	AT	

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